

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ROXANE LABORATORIES, INC.,

Plaintiff,

vs.

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE,

Defendant.

CASE NO.

COMPLAINT

I. NATURE OF THE CASE

1. This is an antitrust action by Plaintiff Roxane Laboratories, Inc. ("Roxane Laboratories" or "Plaintiff") seeking actual and treble damages arising out of anticompetitive conduct by Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline plc (hereinafter "GSK" or "Defendant") that delayed Roxane Laboratories' entry into the market for fluticasone propionate, a drug used for treatment of sneezing, runny or stuffy nose, and nasal itching due to allergies or other causes.

2. GSK manufactures and sells Flonase Nasal Spray ("Flonase"), a brand name version of fluticasone propionate. Beginning in 2004, with the expiration of its statutory exclusivity for Flonase approaching, GSK filed the first in a series of groundless citizen petitions and related documents with the Food and Drug Administration ("FDA") in order to forestall Roxane Laboratories' entry into the fluticasone propionate market.

3. GSK's filings with the FDA lacked any legitimate basis and were submitted as part of GSK's corporate strategy to maximize its profits by using any means available—whether illegal or not—to extend the duration of its monopolies for name brand drugs. GSK's employees and agents knew that the FDA would reject the series of petitions, and also knew that the petitions would trigger the FDA's review process, and would provide GSK with an additional period of time during which it would be able to sell Flonase unhindered by any competition in

the marketplace. Notably, in rejecting the filings by GSK, the FDA openly dismissed them as a transparent attempt by GSK to prolong its monopoly on Flonase, stating: "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved."

4. GSK's filings with the FDA were no more than a thinly veiled attempt to frustrate competition and constituted an abuse of the citizen petition process established by Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). By filing objectively baseless petitions with the FDA, with no subjective expectation of success, and solely to obstruct Roxane Laboratories' entry into the fluticasone propionate market, GSK succeeded in delaying sales of Plaintiff's fluticasone propionate and unlawfully extended its monopoly for Flonase to the detriment of Roxane Laboratories.

II. JURISDICTION AND VENUE

5. Roxane Laboratories brings this action under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover damages, including treble damages, costs of suit, and reasonable attorneys' fees for injuries sustained by it resulting from GSK's violation, as alleged herein, of Section 2 of the Sherman Act, 15 U.S.C. § 2.

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and Sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15(a).

7. Venue is proper in this judicial district pursuant to 15 U.S.C. §22 and 28 U.S.C. §1391(b) and (c) in that GSK's United States headquarters is located in this judicial district and GSK transacts business in this judicial district.

III. PARTIES

8. Plaintiff Roxane Laboratories, Inc. is a corporation with its principal offices located in Columbus, Ohio. Roxane Laboratories markets a variety of generic drugs, including Fluticasone Propionate Nasal Spray.

9. Defendant SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal offices located in Philadelphia, Pennsylvania. SmithKline Beecham Corporation

also conducts business under the name of GlaxoSmithKline and is a subsidiary of GlaxoSmithKline plc.

IV. INTERSTATE COMMERCE

10. GSK's efforts to monopolize and restrain competition in the market for fluticasone propionate substantially affected interstate commerce. At all material times, GSK manufactured, promoted, distributed, and sold substantial amounts of Flonase in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

11. At all material times, GSK transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Flonase.

12. GSK's acts were part of and in furtherance of the illegal monopolization scheme alleged herein, and were authorized, ordered or done by GSK's officers, agents, employees or representatives while actively engaged in the management of GSK's affairs.

V. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

13. The Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-392) ("FDCA") sets forth the regulatory framework for FDA approval of drugs marketed and sold in the United States. When a manufacturer seeks approval of a new drug by the FDA, it must file a new drug application ("NDA") which includes, among other items, submission of data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

14. The FDA grants approval of an NDA upon a determination that the drug is safe and effective for its proposed use. The brand name manufacturer may then proceed to market its drug, and is entitled by statute to a period of exclusivity -- as well as supra-competitive profits with its monopoly. Once the exclusivity period ends, the brand name manufacturer loses its legally sanctioned monopoly and faces competition from generic manufacturers.

15. The FDA also provides an expedited review process by which generic manufacturers may file an abbreviated new drug application ("ANDA"). Because brand name

manufacturers have already demonstrated the safety and efficacy of their drug in their NDA, there is no need for generic manufacturers to undertake the same extensive and costly studies to establish the safety and efficacy of the generic version of the drug; generally, ANDA filers may rely on the scientific finding of safety and effectiveness included by the brand name manufacturer in the NDA for the same drug.

16. To obtain approval of an ANDA, a prospective generic manufacturer must demonstrate to the FDA that the generic drug it proposes to market is the "bioequivalent" of the brand named drug. Generally, a demonstration that two drugs are bioequivalent means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. Bioequivalent medications show no significant difference in the rate and extent to which the active ingredient becomes available at the site of action.

17. With respect to certain drugs, such as fluticasone propionate, that are not intended to be absorbed into the blood stream, the FDA "may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference" between the generic drug and the name brand drug. *See* 21 U.S.C. § 355(j)(8)(C).

18. The existing ANDA framework, enacted by Congress in the Drug Price Competition and Patent Term Restoration Act of 1984, and commonly known as the Hatch-Waxman Act, is intended in part to increase the availability of low-cost generic drugs and does so by, among other means, facilitating market entry for generic medications.

19. As a sophisticated participant in the pharmaceutical industry, GSK was at all relevant times aware that once the statutory period of exclusivity ended for Flonase, it would face competition from manufacturers of lower priced generic brands and a corresponding decline in revenue from sales of the drug.

VI. FACTUAL BACKGROUND

A. FDA Approval of Fluticasone Propionate

20. The FDA approved the NDA for GSK's Flonase Nasal Spray for sale in the United States on October 19, 1994, and subsequently approved several supplements to the Flonase NDA in order to add new labeling information, including new indications for use. The active ingredient in Flonase is fluticasone propionate.

21. GSK held a single patent on Flonase, which expired on November 14, 2003, and subsequently received a six-month extension of market exclusivity from the FDA. GSK's exclusive right to market Flonase in the United States expired on May 14, 2004, and upon approval by the FDA, a generic manufacturer could have begun marketing a generic form of Flonase on or after that date.

22. Roxane Laboratories filed an ANDA with the FDA seeking approval to market an AB-rated generic version of Flonase on October 3, 2002, more than a year before GSK's patent expired and more than a year and a half before GSK's statutorily-regulated market exclusivity expired. Roxane Laboratories sought approval to market its generic product upon the expiration of GSK's period of market exclusivity on May 14, 2004.

23. As a sophisticated and long-standing pharmaceutical manufacturer, GSK knew that as the end of its exclusivity for Flonase approached, one or more generic manufacturers would seek approval from the FDA to market a generic version of the drug. GSK also knew that such ANDAs would be filed with the FDA in time for the FDA to carefully consider them and issue approval prior to or concomitant with the expiration of GSK's market exclusivity.

B. GSK Used Citizen Petitions to Impede Generic Competition

24. Congress enacted federal regulations governing the FDA that allow individuals to express genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry. Under these regulations, any person or entity, including a pharmaceutical company, may file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action.

25. Within 180 days of receipt, the FDA Commissioner must respond to each citizen petition and may approve the request in part or in full, deny it, or provide a tentative response with an estimate on a time for a full response.

26. Reviewing and responding to these petitions often requires the use of substantial time and resources because the FDA must, in addition to its already-existing workload:

(a) research the subject matter of the citizen petition; (b) examine scientific, medical, legal, and sometimes economic issues; (c) consider public responses to the citizen petition; and (d) coordinate internal agency review and clearance of the of the petition response. These activities can and do strain the FDA's limited resources.

27. The citizen petitions filed by GSK did not raise legitimate concerns about the safety or efficacy of Roxane Laboratories' ANDA for fluticasone propionate, and instead were used to block its entry into the market and to extend GSK's monopoly on Flonase, thereby preserving the GSK's considerable monopoly profits well beyond the end of its statutorily-granted exclusivity period.

28. Notably, GSK filed its citizen petitions on the eve of FDA approval of Roxane Laboratories' ANDA for a competing AB-rated generic drug, even though GSK could have made the same arguments months, or even years, earlier. This resulted in the delay of final approval of Roxane Laboratories' pending ANDA while the FDA evaluated the merits of GSK's repeated citizen petitions.

29. The resulting delay of generic competition was lucrative for GSK as it faced impending competition from an AB-rated generic drug manufactured by Roxane Laboratories. GSK earned nearly \$2 billion in revenue from sales of Flonase from the time that GSK filed its initial citizen petition on May 19, 2004, until the FDA's approval of Roxane Laboratories' ANDA on February 22, 2006. As these figures suggest, the cost of filing one or more groundless citizen petitions paled in comparison to the value of securing an additional period of monopoly profits.

30. Many informed observers have identified the filing of FDA citizen petitions with anticompetitive intent and effect as a serious problem. For example, Federal Trade Commissioner Jon Leibowitz stated: "The citizen petition process is ripe for abuse. It's no secret that these are filed at the 11th hour, and most are denied.... The cost to file is low, but the benefit to brands is high." Analysts have identified the very citizen petition filed by GSK in this instance as one designed to delay competition by generic drug manufacturers.

31. Citizen petitions, like those filed by GSK, seldom result in any responsive action regarding the proposed ANDA. In recent years, less than 10% of citizen petitions regarding the approvability of generic products led to any change in the FDA's policy on the basis of data or information submitted in the petition. Yet, prior to 2007, the FDA maintained a practice, well known in the pharmaceutical industry, of considering and responding to relevant citizen petitions prior to approval of an ANDA to assure itself that the petitions did not present any new issues or issues of concern.

32. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. §355(q) (the "2007 Amendments"). In pertinent part, the 2007 Amendments provide that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The 2007 Amendments also authorize the FDA to summarily deny any citizen petition whose primary purpose, as determined by the FDA, is to delay competition. Signed into law on September 27, 2007, these revisions were not yet in effect at the time the FDA was considering the petitions at issue in this case.

C. GSK's Unlawful Scheme to Delay Generic Competition for Flonase

33. On May 19, 2004, just days after the expiration of the statutory exclusivity period for GSK's Flonase, and on the eve of what could have been the FDA's approval of Roxane Laboratories' ANDA, GSK filed the first in a series of objectively baseless citizen petitions with the FDA for the express purpose and with the express intent of delaying the FDA's final approval of Roxane Laboratories' ANDA for fluticasone propionate.

34. Over the next year, GSK filed additional objectively baseless submissions with the FDA, including a second Citizen Petition on November 23, 2004, a Petition for Stay of Action on March 25, 2005, and a Supplement to the Citizen Petition on June 16, 2005.

35. On February 22, 2006, the FDA rebuffed GSK's various citizen petitions (and related documents) in a 24-page letter, finding them to be without merit. In this letter, the FDA chastised the company and its motives, writing "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved." The FDA approved Roxane Laboratories' ANDA for fluticasone propionate on the same day.

36. GSK's filing of the objectively baseless citizen petitions, and related documents, described herein, was part of a broader pattern or practice by GSK to utilize groundless litigation as a mechanism to frustrate competition posed by generic drugs and preserve GSK's highly profitable monopolies on brand name drugs.

1. GSK's First Citizen Petition Was Objectively Baseless

37. On May 19, 2004, five days after its exclusivity period for Flonase expired, but more than a year and a half after Roxane Laboratories filed its ANDA for a generic version of the drug, GSK filed an objectively baseless citizen petition with the FDA. ("First Petition").

38. While acknowledging that the FDA "may be nearing an approval decision on an ANDA" for generic fluticasone propionate, GSK's First Petition did not address the adequacy of Roxane Laboratories' ANDA, present any evidence that Roxane Laboratories' ANDA failed to demonstrate bioequivalence to Flonase, or raise any concerns about public health — the issues for which citizen petitions were primarily implemented.

39. Instead, GSK's First Petition urged the "FDA to expeditiously issue a final guidance document setting forth a valid methodology for assessing the bioequivalence of nasal spray products, prior to approving ANDAs for generic versions of Flonase."

40. GSK knew that the FDA was not required by law, regulation or prior practice to finalize relevant guidance documents prior to approving a pending ANDA or taking other

administrative action, and could not reasonably have expected to prevail on the substance of the First Petition.

41. The FDA rejected GSK's First Petition, stating: "Neither the Act nor FDA regulations require FDA to issue final guidance prior to approving an ANDA.... GSK has cited no authority to support its position that the Agency must complete a guidance document prior to approving an ANDA for a fluticasone propionate nasal spray product...."

2. GSK's Second Petition Was Objectively Baseless

42. On November 23, 2004, six months after the filing of its First Petition, GSK submitted a second objectively baseless citizen petition ("Second Petition") with respect to fluticasone propionate to the FDA. GSK could not reasonably have expected to prevail on the substance of the Second Petition.

43. GSK's Second Petition demanded that the FDA refrain from approving an ANDA for fluticasone propionate unless the proposed generic was shown to meet the same standards related to droplet size distribution ("DSD") and spray pattern ("SP") as that imposed in connection with GSK's NDA supplement for Flonase that was approved by the FDA in October 2004.

44. Like its previous submission, GSK's Second Petition neither addressed the adequacy of Roxane Laboratories' ANDA nor presented any evidence that Roxane Laboratories' fluticasone propionate failed to demonstrate bioequivalence with Flonase. It also failed to raise any concerns about public health.

45. GSK knew that its arguments were objectively baseless. Flonase was approved by the FDA in 1994 without specifications for DSD and SP. As part of a 1999 supplement to its NDA, GSK submitted specifications for DSD and SP. Prior to the time that GSK's 1999 NDA supplement was approved by the FDA in October 2004, and during the entire time GSK worked with the FDA to modify its SP and DSD parameters, GSK continued to market Flonase as a safe and effective product.

46. GSK also knew that because of the proprietary nature of the quality tests and methodologies it had employed with respect to Flonase, and the fact that the standards imposed on Flonase were dependent to a degree on those proprietary tests, it was asking the FDA to impose a nearly impossible standard on any ANDA submission.

47. The FDA rejected GSK's Second Petition, stating: "[e]ach firm develops its own proprietary product quality tests (e.g., to measure DSD and SP) that may use different equipment under different conditions. Because GSK's DSD and SP product quality tests and methodologies are proprietary, it is virtually impossible for a generic manufacturer to perform the exact same tests that GSK used for Flonase approval to compare test and reference products.... ANDA applicants are not expected to have exactly the same product quality specifications as the [NDA product]."

3. GSK's Petition for Stay of Action Lacked Any Legitimate Basis

48. On March 25, 2005, GSK filed a Petition for Stay of Action ("Petition for Stay") seeking a stay of three business days beyond the point in time when GSK was notified of the FDA's decision to grant final approval of any ANDA for a generic version of Flonase.

49. GSK, at the time it filed its Petition for Stay, was aware that Federal regulations at 21 C.F.R. §10.35(e) set out the standard for review of a petition for stay of action to the FDA and provided that such a stay may only be granted if the petitioner demonstrates: (1) it will suffer irreparable harm; (2) its case is not frivolous and is being pursued in good faith; (3) it has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests.

50. GSK failed to provide any legitimate basis in its two prior petitions for the FDA to delay approval of any ANDA for fluticasone propionate, and given the FDA's statutory mandate to approve all generic drugs that meet statutory requirements, GSK could not reasonably have expected to prevail in its request for a stay. Instead, GSK submitted the Petition for Stay to delay the FDA's approval of Roxane Laboratories' pending ANDA by requiring the FDA to consider and respond to the filing.

51. The FDA recognized GSK's Petition for Stay as baseless, finding that "GSK has not articulated sound public policy grounds for supporting a stay." The FDA noted that "[an assumption underlying GSK's argument is that the Agency's approval standards will, upon further examination, be found inadequate. This assumption is too speculative and too unlikely to form the basis of a public policy argument for grant of a stay."

52. Finally, the FDA, finding the merits of GSK's challenges "unpersuasive," explicitly recognized GSK's attempt to monopolize the market and reprimanded the company stating: "[t]he policies behind Hatch-Waxman dictate that GSK should not be permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved under section 505(j) of the Act."

4. GSK's Supplement to the Citizen Petition Lacked Any Legitimate Basis

53. On June 6, 2005, GSK filed an objectively baseless supplement to the First Petition with the FDA ("Supplement"). Consistent with its prior filings with the FDA, GSK's Supplement neither addressed the adequacy of Roxane Laboratories' ANDA nor presented any evidence that Roxane Laboratories' fluticasone propionate lacked bioequivalence to Flonase. GSK's Supplement similarly failed to raise any concerns about public health.

54. Instead, GSK's Supplement included a declaration from a GSK statistician who had reviewed publicly available study data from FDA bioequivalence analyses of a number of generic nasal solution products. Based on the submitted declaration, GSK asserted that the FDA inconsistently applied statistical methods for comparative in vitro tests for ANDAs for nasal spray solution products. GSK knew, however, that its assertions were without merit because Flonase (a nasal suspension product) was not a part of the class of nasal spray solution products described in the declaration it submitted with its Supplement.

55. Like its other filings, GSK's Supplement lacked any legitimate basis. GSK could not reasonably have expected to prevail based on the issues raised in this Supplement. In the 2003 Draft Guidance, the FDA established that it was appropriate to use the Population

Bioequivalence ("PBE") method to review and evaluate in vitro studies related to nasal spray suspension products. This was the same method that GSK's expert criticized.

56. The FDA rejected GSK's Supplement, stating that "GSK's arguments...are not relevant to the fluticasone propionate nasal spray suspension products evaluated under the PBE method."

5. GSK's Anticompetitive Actions Harmed Competition

57. On February 22, 2006, the FDA rebuffed GSK's various filings in a 24-page letter, finding the petitions to be without merit and chastising the company and its motives, explaining "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved." On the same date, the FDA issued an approval of Roxane Laboratories' ANDA for fluticasone propionate.

58. After the FDA rejected its arguments, GSK sought a preliminary injunction seeking to reverse the FDA's denial of its citizen petitions and to enjoin Roxane Laboratories' sales of fluticasone propionate. The court denied GSK's motion for preliminary injunction on March 6, 2006.

59. Roxane Laboratories was unable to begin selling generic Flonase in the United States until March 6, 2006, approximately twenty-two months after GSK's statutorily-granted market exclusivity expired. Thus, GSK's submissions had their desired effect: extending the company's monopoly on Flonase in the United States by nearly two years.

60. GSK did not make its series of submissions to the FDA to influence FDA policy or address any legitimate concern about the efficacy or safety of Roxane Laboratories' generic fluticasone propionate. Rather, GSK intended to forestall Roxane Laboratories' entry into the United States market for fluticasone propionate during the time it would take the FDA to evaluate and respond to the citizen petitions and related documents.

61. GSK's pattern of conduct, under the totality of the circumstances, demonstrates that it intended to and did use the citizen petition process itself, as opposed to the outcome of that process, as an anti-competitive weapon.

62. GSK's unlawful conduct delayed Roxane Laboratories' entry into the U.S. market, foreclosed sales of its fluticasone propionate, and impaired free and unrestrained competition in the United States market.

VII. RELEVANT MARKET

63. The relevant product market is all fluticasone propionate products (including Flonase in all its forms and dosage strengths) and AB-rated bioequivalent fluticasone propionate products. The relevant geographic market is the United States and its territories.

64. GSK had monopoly power over the price of fluticasone propionate in the United States. As the only seller of fluticasone propionate products in the United States prior to March 2006, GSK could impose significant non-transitory price increases without losing sufficient sales to render the price increases unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it was without generic competition.

65. Prior to the entry of generic versions of Flonase into the U.S. market in March 2006, GSK held a 100% market share in the relevant product and geographic markets. Following market entry by Roxane Laboratories, GSK's market share for fluticasone propionate products declined dramatically in a short period of time.

VIII. MARKET EFFECTS

66. GSK's acts and practices, as herein alleged, had the purpose and effect of unreasonably restraining and injuring competition by protecting Flonase from generic competition in the relevant market.

67. GSK's unlawful exclusionary conduct delayed the sale of Roxane Laboratories' fluticasone propionate in the United States, and enabled GSK to sell its Flonase at artificially inflated prices. Absent GSK's conduct, Roxane Laboratories would have been able to market its fluticasone propionate earlier than March 6, 2006.

68. By its course of anticompetitive conduct, including the filing of objectiely baseless citizen petitions, and related documents, described above, GSK injured Roxane Laboratories in its business and property, and GSK also impaired competition by causing

consumers to pay more for fluticasone propionate products than they otherwise would have paid had there been genuine competition. GSK's unlawful conduct deprived Roxane Laboratories and consumers of fluticasone propionate products of the benefits of competition that antitrust laws were intended to preserve.

COUNT ONE – Monopolization in Violation of Section 2 of the Sherman Act

69. Plaintiff incorporates by reference the foregoing allegations as if set forth herein.

70. Defendant achieved and maintained its monopoly power by unlawful, exclusionary means that were designed to defeat competition. These means included the repeated filing of objectively baseless citizen petitions, and related documents, with the FDA.

71. The goal, purpose, and effect of GSK's conduct was to prevent, delay, and/or minimize the success of the entry of Roxane Laboratories' generic fluticasone propionate in the United States.

72. Defendant's exclusionary conduct substantially affected competitive conditions in the relevant market by preventing timely entry of Roxane Laboratories' fluticasone propionate into the market in the United States, and thereby allowing GSK to limit supply and extract monopoly prices.

73. By reason of Defendant's antitrust violation, Plaintiff has been injured in its business and property. Plaintiff was prevented from marketing its fluticasone propionate in the relevant market in a timely manner. Plaintiff's injury is the type of injury the antitrust laws were designed to prevent and flows from that which makes Defendant's conduct unlawful.

74. GSK's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for fluticasone propionate in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant and for the following relief:

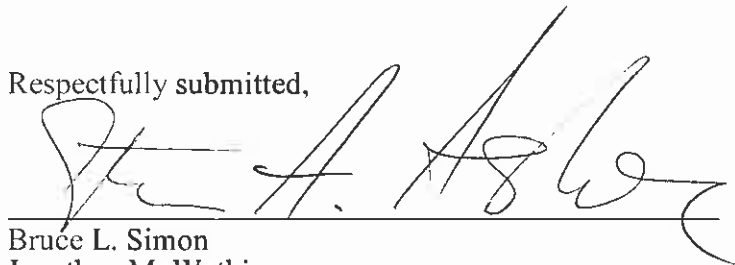
1. Plaintiff be awarded for actual and treble the damages sustained by Plaintiff, as determined by a jury, and judgment entered against Defendant and in favor of Plaintiff;
2. A declaration that the conduct alleged herein was a violation of Section 2 of the Sherman Act;
3. The costs of this suit, including reasonable attorneys' fees; and
4. Such other and further relief as this Court deems just and proper.

X. JURY TRIAL DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this complaint so triable.

DATED: April 17, 2009

Respectfully submitted,



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